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		ED OFFICE (DO/EO/US)	U.S. APPLICATION NO. (II known, see 37 CLR 1.5
*		NG UNDER 35 U.S.C. 371	10/088692
	NATIONAL APPLICATION NO. DK00/00517	INTERNATIONAL FILING DATE 19 September 2000 ()	PRIORITY DATE CLAIMED 21 September 1999
TITLE (Sock	OF INVENTION or Stocking for Thera	peutic Use	
APPLIC Bent	ANT(S) FOR DO/EO/US e K.Y. MERRILD and Lud	vig N. NIELSEN	
Applicar	it herewith submits to the United St	ates Designated/Elected Office (DO/EO/US)	the following items and other information:
1. 🗴	This is a FIRST submission of items	s concerning a filing under 35 U.S.C. 371.	
2. 🔲 -	This is a SECOND or SUBSEQUEN	VI submission of items concerning a filing u	nder 35 U.S.C. 371.
	items (5), (6), (9) and (21) indicated		
		ration of 19 months from the priority date (A	article 31).
	A copy of the International Applicat a. X is attached hereto (require)	d only if not communicated by the Internation	nal Bureau).
i .	b. has been communicated by		
		ication was filed in the United States Receiving	ing Office (RO/US).
6. 🔲 .	An English language translation of t	he International Application as filed (35 U.S	.C. 371(e)(2)).
, grant,	a is attached hereto.		
7		itted under 35 U.S.C. 154(d)(4).	25 110 (2 251/ 1/2))
1 7. □ .		ternational Aplication under PCT Article 19	
The special state of the speci	=	red only if not communicated by the Internati by the International Bureau.	onal Burcau).
E COLON		ever, the time limit for making such amendm	ents has NOT expired
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·		he amendments to the claims under PCT Art	icle 19 (35 U.S.C. 371 (e)(3))
] ≟ 9. □	An oath or declaration of the invent	or(s) (35 U.S.C. 371(c)(4)).	
70	An English lanugage translation of (Article 36 (35 U.S.C. 371(c)(5)).	he annexes of the International Preliminary E	Examination Report under PCT
ij Item	s 11 to 20 below concern documen	at(s) or information included:	
	An Information Disclosure Staten		
12.		rding. A separate cover sheet in compliance	with 37 CFR 3.28 and 3.31 is included.
13.区	A FIRST preliminary amendment		
14.	A SECOND or SUBSEQUENT	oreliminary amendment.	
15.	A substitute specification.		
16.	A change of power of attorney an	d/or address letter.	
17.	A computer-readable form of the	sequence listing in accordance with PCT Rul	e 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18.	A second copy of the published in	nternational application under 35 U.S.C. 154((d)(4).
19.	A second copy of the English lan	guage translation of the international applicat	tion under 35 U.S.C. 154(d)(4).
20.	Other items or information.		
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page 1 of 2

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

MERRILD et al.

Serial No.: To be assigned

Filed: March 21, 2002

For: SOCK OR STOCKING FOR THERAPEUTIC USE

PRELIMINARY AMENDMENT

To the Director of Patents and Trademarks Sir:

Before considering this application, kindly amend the application as follows:

In the Abstract:

Kindly consider the abstract on the cover sheet of published PCT Application WO 01/21119 A1.

In the Specification:

Page 1, after the title and before line 1, insert:

--This application claims the benefit of Danish Application No. PA 1999 01339 filed September 21, 1999 and International Application No. PCT/DK00/00157 filed September 19, 2000.

--BACKGROUND OF THE INVENTION--;

before line 38, insert:

--SUMMARY OF THE INVENTION --.

Page 3, before line 25, insert:

--BRIEF DESCRIPTION OF THE DRAWINGS--;

before line 37, insert:

--DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS-In the Claims:

Kindly amend claims 1-10 as follows:

- 1. (Amended) Sock or stocking for therapeutic use, where the therapeutic treatment consists essentially of a partial covering and relieving of pressure on particularly exposed points or areas of the foot, using a pressure-relieving pad of soft elastomeric material which is placed over the affected area of the foot and fixed with the aid of an elastic bandage which surrounds the foot or at least that part of the foot containing the exposed (tender) point, and which surrounding bandage is comprised of an essentially foot-shaped sock or stocking made of thin flexible and mainly also elastic material (textile of natural or artificial fibers), wherein a number of elastomeric, pad-like inserts are fastened to the inner surface of the toe cavities in the foot-shaped sock or stocking in order to relieve pressure on the inner sides of the toes.
- 2. (Amended) Sock or stocking as defined in claim 1, wherein the elastomeric inserts are made of a soft, almost viscous plastic, for example of a known silicone-based gel type, which inserts are fixed on the inner side of the bandage by thermal welding, sewing, adhesion or in another suitable manner.
- 3. (Amended) Sock or stocking as defined in claim 1, wherein the sock or the stocking itself is made of NYLON or an

equivalent thin and elastic textile, mainly of a type which has an appropriate permeability to water vapor and which occupies as little space and causes as little inconvenience as possible.

- 4. (Amended) Sock or stocking as defined in claim 1, wherein the bandage, i.e. the foot-shaped sock or stocking, is designed with separate cavities for the individual toes (i.e., cavities analogous to the "fingers" in a glove), and the placing of elastomeric inserts on the inner sides of these cavities designed for therapeutic relieving of pressure on tender points on the toes, mainly in the spaces between the toes.
- 5. (Amended) Sock or stocking as defined in claim 4, wherein the toe cavities in question are open at the ends, the bandage terminating at the outer joints of the toes so that the outer joints of the toes with toenails protrude beyond the bandage, and wherein elastomeric inserts are positioned between all toes, and mainly also opposite the bunions on the inner and outer sides of the forefoot, and that the bandage extends back to about the middle of the forefoot.
- 6. (Amended) Sock or stocking as defined in claim 4, wherein the elastomeric inserts in the toe cavities are each a circular, ring-shaped encircling of the toe in question.
- 7. (Amended) Sock or stocking as defined in claim 4, wherein the bandage is prolonged backwards into an actual sock, so that the bandage both encircles the forefoot and the heel, and wherein various inserts are placed in the sock in addition to the toe inserts according to the patient's needs, which inserts can,

for example, include: one or more inserts opposite the heel, an insert for the entire length of the sole, and inserts opposite both ankle protuberances.

- 8. (Amended) Sock or stocking as defined in claim 4, wherein the bandage has an increased length, mainly with termination immediately below knee height, i.e., as a knee-length stocking.
- 9. (Amended) Sock or stocking as defined in claim 1, wherein the elastomeric inserts contain a drug which is successively released during the therapeutic treatment either by diffusion, evaporation or otherwise dissolving.
- 10. (Amended) Sock or stocking as defined in claim 9, wherein the drug in question is a hormone, an antibiotic e.g. to heal sores, a morphine preparation for the treatment of pain in combination with the soothing effect of the pad, or other medication appropriate to the purpose.

REMARKS UNDER 37 C.F.R. 1.111

Consideration and allowance are respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

Entry of the amendment and consideration and allowance of all claims are respectfully requested.

Respectfully,

James C. Wray, Reg. No. 22,693

Meera P. Narasimhan, Reg. No. 40,252

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Suite 300

McLean, Virginia 22101 Tel: (703) 442-4800 Fax: (703) 448-7397

March 21, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1-10 have been amended as below:

- 1. (Amended) Sock or stocking for therapeutic use, where the therapeutic treatment consists essentially of a partial covering and relieving of pressure on particularly exposed points or areas of the foot, using a pressure-relieving pad of soft elastomeric material which is placed over the affected area of the foot and fixed with the aid of an elastic bandage which surrounds the foot or at least that
- [2.] part of the foot containing the exposed (tender) point, and which surrounding bandage is comprised of an essentially foot-shaped sock or stocking [1, 7] made of thin flexible and mainly also elastic material (textile of natural or artificial [fibres] fibers), [characterised by the fastening of] wherein a number of elastomeric, pad-like inserts [3, 5, 6] are fastened to the inner surface of the toe cavities in the foot-shaped sock or stocking in order to relieve pressure on the inner sides of the toes.
- 2. (Amended) Sock or stocking as defined in claim 1, [characterised by] wherein the elastomeric inserts [being] are made of a soft, almost viscous plastic, for example of a known silicone-based gel type, which inserts are fixed on the inner side of the bandage by thermal welding, sewing, adhesion or in another suitable manner.
- 3. (Amended) Sock or stocking as defined in claim 1, [characterised by] wherein the sock [(1)] or the stocking [(7)]

itself [being] <u>is</u> made of NYLON or an equivalent thin and elastic textile, mainly of a type which has an appropriate permeability to water [vapour] <u>vapor</u> and which occupies as little space and causes as little inconvenience as possible.

- 4. (Amended) Sock or stocking as defined in [claims 1, 2 or 3] claim 1, [characterised by] wherein the bandage, i.e. the foot-shaped sock or stocking, [being] is designed with separate cavities [(2)] for the individual toes (i.e., cavities analogous to the "fingers" in a glove), and the placing of elastomeric inserts [(3)] on the inner sides of these cavities designed for therapeutic relieving of pressure on tender points on the toes, mainly in the spaces between the toes.
- 5. (Amended) Sock or stocking as defined in claim 4, [characterised by] wherein the toe cavities in question [(2) being] are open at the ends [(2a)], the bandage terminating at the outer joints of the toes so that the outer joints of the toes with toenails protrude beyond the bandage [(1)], [that] and wherein elastomeric inserts are positioned between all toes, and mainly also opposite the bunions on the inner and outer sides of the forefoot, and that the bandage extends back to about the middle of the forefoot [(Fig. 1)].
- 6. (Amended) Sock or stocking as defined in [claims 4 or 5] <u>claim 4</u>, [characterised by] <u>wherein</u> the elastomeric inserts [(4)] in the toe cavities [(2)] <u>are</u> each [being] a circular, ring-shaped encircling of the toe in question.

- 7. (Amended) Sock or stocking as defined in [one or more of claims 4, 5 or 6] claim 4, [characterised by] wherein the bandage [being] is prolonged backwards into an actual sock, so that the bandage both encircles the forefoot and the heel, and [that] wherein various inserts are placed in the sock in addition to the toe inserts [(3)] according to the patient's needs, which inserts can, for example, include: one or more inserts [(8)] opposite the heel, an insert for the entire length of the sole [(lamina insert 9)], and inserts opposite both ankle protuberances [(inserts 8)].
- 8. (Amended) Sock or stocking as defined in [one or more of claims 4-7] claim 4, [characterised by] wherein the bandage [having] has an increased length, mainly with termination immediately below knee height, i.e., as a knee-length stocking [(7)].
- 9. (Amended) Sock or stocking as defined in [claims 1 and 2] claim 1, [characterised by] wherein the elastomeric inserts [containing] contain a drug which is successively released during the therapeutic treatment either by diffusion, evaporation or otherwise dissolving.
- 10. (Amended) Sock or stocking as defined in claim 9, [characterised by] wherein the drug in question [being] is a hormone, an antibiotic e.g. to heal sores, a morphine preparation for the treatment of pain in combination with the soothing effect of the pad, or other medication appropriate to the purpose.

WO 01/21119

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Sock or Stocking for Therapeutic Use.

The invention is a sock or stocking for therapeutic use, more specifically as defined in the introduction to claim 1.

It is known that coms, bunions and related pressure sore problems on the feet can be treated with pressure-relieving dressings consisting of a soft elastomeric pad which is held in position over the affected point on the foot with the aid of an elastic bandage or a plaster. The exposed and often highly pressure-sensitive part of the foot is thus protected against direct external pressure and against the imitation which, for example, can be caused by friction against the shoe, or, in the case of a pressure sore on the inner side of a toe, by rubbing against the neighbouring toe. The elastomeric insert or pad is usually made of a soft, almost viscous plastic. This plastic, which, for example, can consist of a silicone-based gel or another appropriate elastomer, is characterised by being extremely soft and workable, and ensures an optimal relief of pressure via this property and alleviation at the point of tendemess. The insert is usually shaped (prefabricated) as a flat circular piece which is placed over the tender point and fixed with the aid of the bandage as specified above. The insert or pad is referred to below as a pad.

The known technique is usable for the treatment of a single bunion or a single pressure sore of limited physical extent, but in practice it is a problem that the bandage used to fix the pad is often very bulky, as a result of which the dressing itself can be a source of irritation and can, at worst, cause new pressure sores. The known treatments for relief of pressure are unsuitable for the prophylactic treatment of patients who are known to have a substantial risk of developing. pressure scres on the feet, such as patients with diabetes, heart patients and patients with paralysis, because prophylactic use of the known forms of treatment will of its very nature assume a large number of individual dressings and pads on the foot at the same time, and this is of course not possible in practice without major inconvenience for the patient.

U.S. patent no. 5,823,195 describes a therapeutic stocking with two ankle inserts. The two ankle inserts protect the ankle and the area around it down to the heel against the formation of sores. The elastic stocking ensures an even pressure distribution over the relevant part of the foot. The ankle inserts are made of a silicone elastomer and are hydrophobic. For obvious reasons the therapeutic stocking is unsultable for use in prophylactic treatment to prevent pressure sores between the loes. The ankle inserts are placed in the therapeutic stocking as loose inserts. In practice this is done by the patient first putting on the stockings, after which the inserts are placed in them. The procedure is labonous and means that many patients, for example those with restricted ability to move or with paralysis, will have difficulty completing the task without assistance.

The object of the invention was to devise an improved form of pressure-relieving bandage or dressing which, based on known forms of treatment using point-wise relief of pressure on particularly exposed areas of the foot, would enable simultaneous relief of pressure at a number

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of points or areas of the foot. An attempt was also made to find a solution which can be used in everyday life as normal preventive treatment for the patients at special risk discussed above, so that these patients' problems with pressure sores on the feet and between the toes can be prevented simply and effectively. The invention's pressure-relieving bandage must be easy to put on and take off, the bandage must be able to be worn discreetly under the clothing (under stockings or similar), and the bandage may not cause discomfort or other forms of inconvenience to patients. These and other benefits are achieved in the invention by equipping the dressing as specified in the characterising part of claim 1.

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The new element in the invention is that a number of elastomeric, pad-like inserts are fastened, opposite the area(s) of the foot on which pressure is to be relieved, on the inner side of the foot-shaped sock or stocking, which is appropriately made of thin flexible and mainly also elastic material (textile of natural or artificial material). With a single bandage, the patient can thus gain pressure relief in a single action at all points on the foot which are liable to the formation of sores (pressure sore problems) or which are tender or exposed to pressure for other reasons. The bandage is simple for the patient to apply, thanks to the textile material's elasticity and the bandage's foot-shaped form. The elastomeric inserts attached to the inner side of the bandage will immediately sit "correctly" in relation to the areas of the foot which are exposed to pressure when the bandage is pulled on, and in particular the pads which are to protect the inner sides of the toes and the outer sides of the joints are positioned correctly solely because of the bandage's "foot shape". During use, the bandage ensures that the pads are held in their correct relative positions and that the pads do not shift unintentionally relative to their various pressure points. The bandage's main use will be for prophylactic purposes.

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The invention's elastometic inserts are suitably made of a soft, almost viscous plastic, for example a known silicone-based gel-like type. Alternatively, the insert can be made of foamed plastic, foam rubber, natural rubber or another appropriate material. The elastometic inserts are fastened to the inner side of the bandage by thermal welding, sewing, adhesion or other appropriate method. The sock or stocking itself is made of NYLON or an equivalent thin and elastic textile, mainly of a type with a suitable permeability to water vapour and which takes as little space and causes as little inconvenience as possible so that the bandage can be worn under ordinary footwear (socks, stockings, shoes etc.) without inconveniencing the patient.

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In one preferred embodiment of the invention, the bandage is equipped with separate cavities for the individual toes, that is, cavities analogous to the "fingers" in a glove. The inner sides of these toe cavities carry elastomeric inserts dimensioned for therapeutic pressure relief on the inner sides of the toes, that is, in the spaces between the toes. Experience has shown that these areas of the feet are highly susceptible to the formation of pressure sores. The bandage makes it possible to relieve the pressure on the exposed areas in a very gentle and yet effective

Examples of preferred embodiments of the bandage according to the invention are given in claims 5-8. The bandage itself can be shaped like a full sock, a half sock or a knee-high stocking as required, and the elastomeric inserts can be freely placed in the bandage according to where there is a need for pressure relief. Claim 8 concerns an embodiment equipped with full foot lamina, that is, where the elastomeric insert almost forms an internal sole in the bandage. This form of therapeutic stocking is used with advantage by patients with fallen arches.

To increase the therapeutic effect of the bandage, the invention makes it possible to supplement the pressure-relieving effect with some form of medication. This requires the measures specified in claims 9 and 10, which consist of the elastomeric inserts containing a drug which is released successively to the patient during the treatment, either by diffusion, evaporation or otherwise dissolving. Under the invention the drug can be a hormone, an antibiotic e.g. for the healing of sores, a morphine preparation to treat pain in combination with the soothing effect of the pad, or other appropriate medication.

A more detailed description of the invention is now given in association with the drawings, of which

- Fig. 1 shows a forefoot bandage according to the invention with pressure pads inserted between the toes, viewed obliquely from the front, in use on a patient.
- Fig. 2 The same separately, viewed obliquely from above.
- Fig. 3 The forefoot bandage viewed directly from the front.
- Fig. 4 A magnified section which shows a toe section of the bandage with associated pressure pads.
- 30 Fig. 5 The same in cross-section.
 - Fig. 6 The same in an embodiment with circular ring-shaped pressure pad which completely surrounds the toe.
 - Fig. 7 A stocking-shaped, knee-length bandage according to the invention viewed obliquely from the side.
- 35 Fig. 8 The underside of the same with the foot lamina Insert marked.

In the embodiment shown in Figs. 1-5, the sock or stocking consists principally of an elastic bandage 1 in the shape of a "foot glove", designed to cover the forefoot from the outer joints of the toes to about the middle of the forefoot as shown. The bandage is called a forefoot sock.

40 The bandage, which is made of an elastic textile material (NYLON or equivalent), has separate

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"fingers" for the toes, that is, cavilies 2 in which the toes fit when the stocking is put on. These "fingers" or cavilies 2 are open at the ends 2a, so that the outer joints of the toes are not covered by the bandage. Experience shows that the outer joints seldom suffer pressure sores or similar problems.

The bandage is equipped on the inner side with elastomeric inserts 3 at the points where pressure on the foot and the toes is to be relieved. In the embodiment shown there are several separats inserts 3 in the actual toe cavities 2, designed to relieve the pressure of the inner sides of the toes against each other. The inserts are shaped as circular or rectangular pads which are fastened to the inner side of the bandage by sewing, thermal welding or adhesion. Alternatively, the inserts on the toe cavities 2 can be ring-shaped (insert shown in 4) to completely encircle the toe when the bandage is put on (Fig. 6). Inserts placed opposite bunions, i.e. on the outer sides of the big and the little toes, can also be used in the forefoot stocking in question (inserts 5 and 6).

Figs. 7 and 8 show the bandage in a knee-length embodiment 7, but still with separate cavities for the toes which are open at the ends 2. Apart from the toe inserts 3 already discussed, the knee-length stocking can be equipped with inserts 8 opposite the heel and opposite both ankle protuberances. In a special embodiment this knee-length stocking can also be equipped with a full foot lamina 9 of elastomeric material designed for therapeutic treatment of patients with fallen arches. In other embodiments not figured here, the bandage can be shaped like a short sock and fitted with inserts combined in various ways according to the patient's individual needs. The inserts can, as already discussed, contain a drug which is successively released during the treatment via the pad's direct contact with the skin.

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- 1. Sock or stocking for therapeutic use, where the therapeutic treatment consists essentially of a partial covering and relieving of pressure on particularly exposed points or areas of the foot, using a pressure-relieving pad of soft elastomeric material which is placed over the affected area of the foot and fixed with the aid of an elastic bandage which surrounds the foot or at least that
- 2. part of the foot containing the exposed (tender) point, and which surrounding bandage is comprised of an essentially foot-shaped sock or stocking 1, 7 made of thin flexible and mainly also elastic material (textile of natural or artificial fibres), characterised by the fastening of a number of elastomeric, pad-like inserts 3, 5, 6 to the inner surface of the toe cavities in the foot-shaped sock or stocking in order to relieve pressure on the inner sides of the toes.
- 2. Sock or stocking as defined in claim 1, characterised by the elastometric inserts being made of a soft, almost viscous plastic, for example of a known silicone-based gel type, which inserts are fixed on the inner side of the bandage by thermal welding, sewing, adhesion or in another suitable manner.
- 3. Sock or stocking as defined in claim 1, characterised by the sock (1) or the stocking (7) Itself being made of NYLON or an equivalent thin and elastic textile, mainly of a type which has an appropriate permeability to water vapour and which occupies as little space and causes as little inconvenience as possible.
- 4. Sock or stocking as defined in claims 1, 2 or 3, characterised by the bandage, i.e. the foot-shaped sock or stocking, being designed with separate cavities (2) for the individual toes (i.e., cavities analogous to the "fingers" in a glove), and the placing of elastomeric inserts (3) on the inner sides of these cavities designed for therapeutic relieving of pressure on tender points on the toes, mainly in the spaces between the toes.
- 5. Sock or stocking as defined in claim 4, characterised by the toe cavities in question (2) being open at the ends (2a), the bandage terminating at the outer joints of the toes so that the outer joints of the toes with toenails protrude beyond the bandage (1), that elastomeric inserts are positioned between all toes, and mainly also opposite the bunions on the Inner and outer sides of the forefoot, and that the bandage extends back to about the middle of the forefoot (Fig. 1).
- 6. Sock or stocking as defined in claims 4 or 5, characterised by the elastomene inserts (4) in the toe cavities (2) each being a circular, ring-shaped encircling of the toe in question.

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- 7. Sock or stocking as defined in one or more of claims 4, 5 or 6, characterised by the bandage being prolonged backwards into an actual sock, so that the bandage both encircles the forefoot and the heel and that various inserts are placed in the sock in addition to the toe inserts (3) according to the patient's needs, which inserts can, for example, include: one or more inserts (8) opposite the heel, an insert for the entire length of the sole (lamina insert 9), and inserts opposite both ankle protuberances (inserts 8).
- 8. Sock or stocking as defined in one or more of claims 4-7, characterised by the bandage having an increased length, mainly with termination immediately below knee height, i.e., as a knee-length stocking (7).
- 9. Sock or stocking as defined in claims 1 and 2, characterised by the elestomeric insens containing a drug which is successively released during the therapeutic treatment either by diffusion, evaporation or otherwise dissolving.
- 10. Sock or stocking as defined in claim 9, characterised by the drug in question being a hormone, an antibiotic e.g. to heat sores, a morphine preparation for the treatment of pain in combination with the soothing effect of the pad, or other medication appropriate to the purpose.

(19) World Intellectual Property Organization International Bureau



(43) International Publication Date 29 March 2001 (29.03.2001)

PCT

(10) International Publication Number WO 01/21119 A1

(51) International Patent Classification?:

A6IF 13/06 (

(21) International Application Number: PCT/DK00/00517

(22) International Filing Date:

19 September 2000 (19.09.2000)

(25) Filing Language:

Danish

(26) Publication Language:

English

(30) Priority Data:

PA 1999 01339

21 September 1999 (21.09.1999) DK

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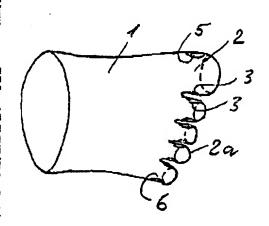
(84) Designated States (regional): ARIPO percut (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TI, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, II, LU, MC, NL, PT, SE), OAPI patent (BF, BI, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TO).

Published:

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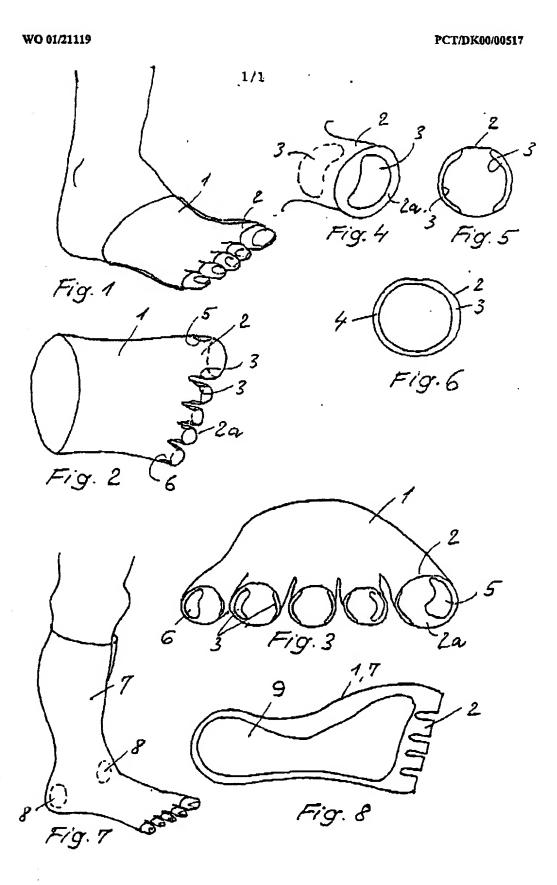
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SOCK OR STOCKING FOR THERAPEUTIC USE



(57) Abstract: The invention relates to a foot-shaped sock or stocking for therapsutic use, made of thin, flexible and preferably also elastic material. To the inner surface of the toe cavities of said foot-shaped sock or stocking are fastened a number of elastomeric, pad-like inserts that relieve pressure on the inner side of the toe. The elastomeric insert according to the invention are suitably made of a soft, almost viscous plastic, for instance of a known silicons-based gal type, said inserts being fastened on the inner side of the bandage by thermal welding, sewing, adhesion or in another suitable way. The sock or stocking itself is made of nylon or an equivalent thin and elastic textile, preferably of a type which has an appropriate permeability to vapour, and which occupies as little space and causes as little inconvenience as possible, so that the bandage can be worn under ordinary footwear.

O 01/21119 A1



PTO/SB/81 (10-00)
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Application Number	10/088,692
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PTO/SB/01 (10-00)
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PATENT APPLICATION	COMPLETE IF KNOWN				
(37 CFR 1.63)	Application Number	10 / 088,692			
7	Filing Date	03/21/2002			
☐ Declaration ☐ Declaration Submitted ☐ OR Submitted after Initial	Group Art Unit	·			
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	My residence, mailing address, and citizenship are as stated below next to my name.									
	I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:									
	Sock or stocking for therapeutic use.									
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1	Additional foreign application	number	s are listed on a	supplemental priority	data sheet PTO/S	B/02B attached	hereto:			
	I hereby claim the benefit under	35 U.S.	.C. 119(e) of an	y United States provis	ional application() listed below.		_		
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